IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

ANITA HOCHENDONER; EARL HOCHENDONER; ANITA BOVA; JOSEPH M. CARIK; BARBARA J. CARIK; MICHAEL MASULA; ERIN MASULA AMBER BRITTON; SHAWN BRITTON; CHERYL BRITTON; THOMAS OLSZEWSKI; DARLENE COOKINGHAM; KYLE WILLINK; TOM STANZIANO; WENDY STANZIANO; RICKY LADD; STACY LADD; STEVE NAMNATH; HEIDI WITTENBERG; and DAVID ROBERTS; Individually and on behalf of all others similarly situated,	)	Civil Action No. 11-0313
Plaintiffs, v.	)	JURY TRIAL DEMANDED
GENZYME CORPORATION; and MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK,	)	
Defendants.	)	

AMENDED COMPLAINT

AND NOW come Plaintiffs Anita Hochendoner, Earl Hochendoner, Anita Bova, Joseph M. Carik, Barbara J. Carik, Michael Masula, Erin Masula, Amber Britton, Shawn Britton, Cheryl Britton, Thomas Olszewski, Darlene Cookingham, Tom Stanziano, Wendy Stanziano, Kyle Willink, Ricky Ladd, Stacy Ladd, Steve Namnath, Heidi Wittenberg, and David Roberts, individually and on behalf of others similarly situated, by and through their attorneys, Kurzweg Law Offices, C. Allen Black, Esq. and Matthew L. Kurzweg, Esq., and, pursuant to Fed.R.C.P. 15(a)(1)(B), file this Amended Complaint.

In support thereof, Plaintiffs aver as follows:

PARTIES

1. Plaintiff Anita Hochendoner is an adult individual who currently resides in Pittsburgh, PA.
2. Plaintiff Earl Hochendoner is an adult individual who currently resides Pittsburgh, PA and is the spouse of Anita Hochendoner.
3. Plaintiff Anita Bova is an adult individual who currently resides in Pittsburgh, PA.
4. Plaintiff Joseph M. Carik is an adult individual who currently resides in North Las Vegas, NV.
5. Plaintiff Barbara J. Carik is an adult individual who currently resides in Pittsburgh, PA and is the spouse of Joseph M. Carik.
6. Plaintiff Michael Masula is an adult individual who currently resides in Pittsburgh, PA.
7. Plaintiff Erin Masula is an adult individual who currently resides in Pittsburgh, PA and is the spouse of Michael Masula.
8. Plaintiff Amber Britton is an adult individual who currently resides in Kirkland, WA.
9. Plaintiff Shawn Britton is an adult individual who currently resides in Edmonds, WA.
10. Plaintiff Cheryl Britton is an adult individual who currently resides Edmonds, WA and is the spouse of Shawn Britton.
11. Plaintiff Thomas Olszewski is an adult individual who currently resides in Grayling, MI.
12. Plaintiff Darlene Cookingham is an adult individual who currently resides in Grayling, MI and is the spouse of Thomas Olszewski.
13. Plaintiff Tom Stanziano is an adult individual who currently resides in Oldsmar, FL.

14. Plaintiff Wendy Stanziano is an adult individual who currently resides in Oldsmar, FL and is the spouse of Tom Stanziano.

15. Plaintiff Kyle Willink is an adult individual who currently resides in Delmar, DE.

16. Plaintiff Ricky Ladd is an adult individual who currently resides in Tecumseh, MI.

17. Plaintiff Stacy Ladd is an adult individual who currently resides in Tecumseh, MI and is the spouse of Ricky Ladd.

18. Plaintiff Steve Namnath is an adult individual who currently resides in San Francisco, CA.

19. Plaintiff Heidi Wittenberg is an adult individual who currently resides in San Francisco, CA and is the spouse of Steve Namnath.

20. Plaintiff David Roberts is an adult individual who currently resides in Goldsboro, NC.

21. Defendant Genzyme Corporation ("Genzyme") is a corporation organized and existing under the laws of the State of Massachusetts, with its headquarters and principal place of business located at 500 Kendall Street, Cambridge, MA 02142, and doing business within the Western District of Pennsylvania and elsewhere in the United States.

22. Defendant Mount Sinai School of Medicine of the City University of New York ("Mt. Sinai") is a corporation organized and existing under the laws of the State of New York, with its headquarters and principal place of business located at One Gustave L. Levy Place, New York, NY 10029-6574. Mt. Sinai holds limited title to and is the sole licensor of U.S. Patent No. 5,356,804 to Genzyme for the manufacture of Fabrazyme®. Mt. Sinai advertises free testing for patients throughout the U.S. that may have Fabry disease.

JURISDICTION AND VENUE

23. Jurisdiction is conferred upon this judicial district pursuant to federal question jurisdiction under 28 U.S.C. §1331. This Court also has diversity jurisdiction pursuant to 28 U.S.C. § 1332(a) (1) because the Plaintiffs are citizens of a State different from one or more Defendants and the aggregate amount in controversy exceeds seventy five thousand ($75,000), exclusive of interest and costs. Jurisdiction is further conferred under 28 U.S.C. §§ 1331 and 1337. This Court also has diversity jurisdiction over the Classes (as hereinafter defined) pursuant to 28 U.S.C. §§ 1332(d) (2) and (6) of the Class Action Fairness Act of 2005 because one or more members of the Classes are citizens of a State different from one or more Defendants and the aggregate amount in controversy exceeds five million dollars ($5,000,000), exclusive of interest and costs.

24. Venue is proper in the Western District of Pennsylvania pursuant to 28 U.S.C. § 1391(a)(2) and(b)(2) because Defendants transact business within this district either by direct sale or underlying license agreements with three of the Plaintiffs, and injury to these three or more of the Plaintiffs occurred in this district.

25. Additional out-of-state Plaintiffs join the instant case under Fed.R.C.P. 20(a)(1)(A) and (B) as all injuries arose from a common fact and present a common question of law.

FACTUAL BACKGROUND

26. Plaintiffs Anita Hochendoner, Anita Bova, Joseph M. Carik, Michael Masula, Amber Britton, Shawn Britton, Thomas Olszewski, Kyle Willink, Tom Stanziano, Ricky Ladd, Steve Namnath and David Roberts suffer from Fabry Disease, which is heritable genetic illness and results in the body

being unable to synthesize the enzyme alpha-galactosidase A, which is critical for the degradation and export of fats from cells.

27. Fabry disease is a life-threatening illness and without treatment results in the premature death of Fabry patients from complications such as renal disease, heart attack, and stroke.

28. Left untreated, Branton *et al.*, "Natural History and Treatment of Renal Involvement in Fabry Disease;" J. Am. Soc. Nephrol. 13:S139-S143 (2002) found from survival analysis that 50% of patients developed End Stage Renal Disease "ESRD" by 53 years, with a range of 21 to 56 years. Importantly, all patients in this National Institute of Health ("NIH") study who lived into their 50s developed ESRD.

29. While no cure for Fabry is yet available, one of the greatest breakthroughs in scientific research on Fabry disease has been the discovery that enzyme replacement therapy with agalsidase beta (Fabrazyme®) can effectively treat Fabry patients.

30. The scientific research on Fabry disease that led to the breakthrough was a direct result of taxpayer funding.

31. Specifically, the NIH awarded grant no. DK 34045 to Dr. Robert J. Desnick ("Desnick") at the Mount Sinai School of Medicine of New York University to develop Fabrazyme® as an enzyme replacement therapy to treat Fabry Disease.

32. Mt. Sinai was granted U.S. Patent No. 5,356,804 to a method of producing agalsidase beta subject to the requirements and obligations of 35 U.S.C. §§ 200-212, commonly known as the Bayh-Dole Act.

33. Mt. Sinai exclusively licensed U.S. Patent No. 5,356,804 for the manufacture of agalsidase beta (Fabrazyme®) to Genzyme Corporation, which is the sole supplier of the drug to the U.S. marketplace.

34. Mt. Sinai advertises ostensibly free testing for Fabry disease to all U.S. residents, hereinafter referred to as the "Mt. Sinai Fabry Testing Program."

35. Desnick, an inventor of Fabrazyme® and an employee of Mt. Sinai, diagnoses Fabry patients under the Mt. Sinai Testing Program.

36. Plaintiff s Michael Masula, a Pennsylvania resident and Thomas Olszewski, a Michigan resident, were diagnosed under the Mt. Sinai Fabry Testing Program.

37. Plaintiff Michael Masula's diagnosis from Mt. Sinai is signed by Desnick and recommends discussion of treatment for Fabry disease as well as informing other family members of the availability of testing for Fabry disease.

38. Positive diagnoses under the Mt. Sinai Testing Program result in both Mt. Sinai and Desnick receiving patent royalties from patients subsequently treated with Fabrazyme®, including Plaintiffs Michael Masula and Thomas Olszewski.

39. Mt. Sinai holds medical records for Fabry patients placed on Fabrazyme® after being diagnosed under the Mt. Sinai Fabry Testing Program, including records for Plaintiffs Michael Masula and Thomas Olszewski.

40. Desnick is a paid consultant for Genzyme as well as being an employee of Mt. Sinai.

41. Mt. Sinai knows of and consents to Desnick's consultations with Genzyme.

42. Desnick consulted with Genzyme at all times relevant hereto, and continues to consult for Genzyme.

43. In April 2003, the Food and Drug Administration "FDA" granted approval for Genzyme to market Fabrazyme® for treatment of Fabry patients.

44. The FDA approval of Fabrazyme® was based on a recommended prescribed dose of 1 mg/kg body weight infused every two weeks as an intravenous (IV) infusion. See FDA approved package insert, attached hereto and incorporated herein as Exhibit A.

45. No other enzyme replacement therapy is approved in the U.S., although a slightly different molecule, designated agalsidase-alfa (Replagal®) is marketed overseas for treatment of Fabry disease.

46. From the date of approval until approximately June 2009, Genzyme was able to manufacture enough Fabrazyme® to treat all currently diagnosed Fabry patients in the U.S.

47. However, sometime before June 2009, Genzyme decreased production of Fabrazyme® as a result of a viral infection in their Allston Landing, MA manufacturing plant.

48. Genzyme caused the viral infection of Fabrazyme® by failing to clean and sterilize their bioreactors between production batches, and thus introduced the virus by cross-contamination.

49. Specifically, Genzyme would use the same bioreactors to produce both Fabrazyme® and a different biological drug, Cerezyme®, which is used to treat another enzyme deficiency termed Gaucher disease.

50. The Cerezyme® production batches were initially contaminated with the non-human Vesivirus 2117.

51. Genzyme then cross-contaminated Fabrazyme® cultures by failing to properly clean and sterilize the bioreactors before switching it for Fabrazyme® production

52. The Allston Landing facility was the subject of a FDA warning letter that followed an inspection in September and October of 2008. One of the FDA's concerns was controls to protect against microbial contamination.

53. Genzyme additionally shifted capital away from production and maintenance of Fabrazyme® stocks, leading to foreseeable insufficient capacity and inventory to mitigate any shortages it would encounter.

54. Further, in November 2009, Genzyme produced Fabrazyme® vials that contained contaminants of particulate steel, glass and rubber.

55. The FDA initiated action against Genzyme which resulted in a consent decree in May 2010, which included a $175 million dollar fine and oversight of the manufacture of Fabrazyme® for at least 7 years.

56. In June 2009, as a direct result of its reduced production of Fabrazyme®, Genzyme unilaterally implemented a rationing plan for its reduced supply of Fabrazyme® for the then known Fabry patients, wherein Genzyme unilaterally limited then known Fabry patients to receiving only less than one-third (1/3) of the recommended prescribed dose ("Genzyme Rationing Plan").

57. By and through the Genzyme Rationing Plan, Genzyme also unilaterally barred any newly diagnosed patients from receiving Fabrazyme®.

58. Physicians only prescribe the recommended dose of 1mg/kg of Fabrazyme® for their patients.

59. Under the Genzyme Rationing Plan, Genzyme refuses to honor U.S. doctors' prescriptions for a full dose of Fabrazyme® for patients thereby forcing U.S. physicians to administer a lowered dose contrary to their best medical judgment

60. The Genzyme Rationing Plan prevents physicians from exercising independent judgment for treating Fabry patients.

61. Until about June 2009, Plaintiffs Joseph M. Carik, Michael Masula, Anita Hochendoner, Anita Bova, Kyle Willink, Tom Stanziano, Ricky Ladd, Steve Namnath, David Roberts, and Thomas Olszewski, and all other then known Fabry patients similarly situated, were receiving the recommended prescribed dose, but after June 2009, Genzyme reduced their respective doses to less than one-third of the FDA approved dose pursuant to the Genzyme Rationing Plan.

62. On or about January 2010, pursuant to the Genzyme Rationing Plan, Genzyme slightly increased doses to only 50% of the recommended prescribed dose to Plaintiffs Joseph M. Carik, Michael Masula, Anita Hochendoner, Anita Bova, Kyle Willink, Tom Stanziano, Ricky Ladd, Steve Namnath, David Roberts, and Thomas Olszewski, and all other then known Fabry patients similarly situated.

63. On March 25, 2011, Genzyme announced they it had destroyed yet another lot of defective Fabrazyme®, leading to another shortage in which patients are expected missed doses for the

months of May and June of 2011.

64. On March, 25, 2011, Genzyme also announced it was reallocating stocks away from U.S. patients to overseas patients, despite overseas patients having access to the alternative treatment, Replagal®.

65. As of this filing, almost two years after the Genzyme Rationing Plan began, Plaintiffs Joseph M. Carik, Michael Masula, Anita Hochendoner, Anita Bova, Kyle Willink, David Roberts, Tom Stanziano, Ricky Ladd, Steve Namnath, Thomas Olszewski, Amber Britton, and Shawn Britton as well as all other Fabry patients similarly situated in the United States being treated with Fabrazyme® do not receive the FDA approved dose from Genzyme as a direct result of the Genzyme Rationing Plan.

66. Plaintiffs Amber Britton and Shawn Britton were diagnosed with Fabry disease after June 2009.

67. Under the Genzyme Rationing Plan, after June of 2009, Genzyme barred all newly diagnosed Fabry patients from receiving any Fabrazyme®.

68. Under the Genzyme Rationing Plan, Genzyme barred Plaintiffs Amber Britton and Shawn Britton and all other Fabry patient similarly situated from receiving Fabrazyme®, despite immediate treatment with Fabrazyme® being medically indicated.

69. As of March 2011, Amber Britton and Shawn Britton began to receive a reduced dose of Fabrazyme®.

70. As of this filing, almost two years after the Genzyme Rationing Plan began, Genzyme still bars Fabrazyme® access to many United States citizens similarly situated and diagnosed with Fabry

disease after June 2009.

71. Defendant Mt. Sinai knew of the Genzyme Rationing Plan, and despite having statutory duties to the contrary described hereinafter, with knowledge, consented to the Genzyme Rationing Plan under its exclusive license agreement with Genzyme and through Desnick's consultations with Genzyme.

72. Genzyme was aware of adverse events and the potential for such adverse events by reducing the dose of Fabrazyme® below FDA approved levels.

73. Similarly, Mt. Sinai as well as its employee, Desnick, were also aware of adverse events and the potential for such adverse events associated with Genzyme's Rationing Plan, but consented and maintained consent for licensing the patent for Fabrazyme® despite having a duty to protect against the invention's unreasonable use and non-use under the Bayh-Dole Act.

74. Mt. Sinai as well as its employee, Desnick, were also aware that that Genzyme banned newly diagnosed patients from receiving Fabrazyme® despite having a duty to protect against the invention's unreasonable use and non-use under the Bayh-Dole Act.

75. Mt. Sinai never informed the NIH of the Genzyme Rationing Plan and the resultant unreasonable use and non-use of the invention secured under the Bayh-Dole act, thereby concealing the violations of the Bayh-Dole act from the NIH.

76. Neither Mt. Sinai nor Genzyme has ever applied for regulatory approval of the Genzyme Rationing Plan or administration of a reduced Fabrazyme® dose to treat Fabry disease.

77. Neither Mt. Sinai nor Genzyme has ever shown that a reduced dose of Fabrazyme® is either safe

or efficacious for treating Fabry disease.

78. Neither Mt. Sinai nor Genzyme has informed doctors or Fabry patients as to what adverse events have been observed or could result from the Genzyme Rationing Plan.

79. On February 17, 2010, Genzyme reported to European Physicians that "All patients, especially those with adjusted dose regimes should be under close clinical surveillance. A medical examination, including all relevant clinical parameters, should be performed every two months. It is of the utmost importance to monitor plasma [globotriaosylceramide] GL-3 or urinary GL-3 levels, as for the moment the GL-3 level is the most sensitive parameter. Patients who demonstrate a deterioration of disease should reinitiate the original treatment with Fabrazyme." See [European] Healthcare Professional Communication (February 17, 2010), attached hereto and incorporated herein as Exhibit B (emphasis added).

80. On April 22, 2010, Genzyme stated that European "physicians are advised to reinitiate the treatment with the original dosing regime or initiate a treatment with alternative approved medicinal product" for those experiencing "aggravation of disease symptoms and/or adverse events ascribed to the lowered dose of Fabrazyme." See [European] Direct Healthcare Professional Communication (April 22, 2010), attached hereto and incorporated herein as Exhibit C (emphasis added).

81. On July 5, 2010, Genzyme reported to European Physicians that "in situations where alternative treatment is not available or where [continuation of] medical treatment with Fabrazyme is deemed medically necessary it is important to note that an increase in clinical manifestations indicative of

Fabry disease progression has been observed on lowered dose." See [European] Direct Healthcare Professional Communication (July 5, 2010), attached hereto and incorporated herein as Exhibit D.

82. On January 21, 2011, Genzyme reported to U.S. physicians that "[b]ecause Fabry disease is a complex condition, there is no clear way to decide which patients are in greatest need of treatment." See RE: U.S. Supply of Fabrazyme® (agalsidase beta) for February – April 2011 (January 21, 2011), attached hereto and incorporated herein as Exhibit E.

83. Genzyme has not disclosed to U.S. doctors or patients the need for medical examinations every two months for U.S. patients despite recommending such a standard of care for European patients.

84. Genzyme has not disclosed to U.S. doctors or patients the need to monitor plasma or urinary GL-3 levels for U.S. patients, despite such monitoring being of "utmost importance" for the standard of care for at least for European patients.

85. Genzyme has not disclosed to U.S. doctors or patients that "clinical manifestations indicative of Fabry disease progression has been observed on lowered dose," despite admitting to European physicians the importance of such observations especially "in situations where alternative treatment is not available" such as the U.S.

86. Genzyme has not advised U.S. physicians to reinitiate the original full dose treatment for U.S. patients that have disease progression, despite advising European physicians to take such action to protect the health and safety of European Fabry patients.

87. Genzyme does not and will not provide drug to U.S. patients to reinitiate treatment with a full dose if they experience disease progression, despite advising and accordingly providing increased drug

access for European patients experiencing disease progression.

88. Genzyme offers the alternative of increasing the dose for European Fabry patients in lieu of switching the patient to the other approved Fabry treatment Replagal®.

89. By offering increased doses to European patients, Genzyme is able to mitigate the erosion of the European market share for Fabrazyme by Replagal®.

90. Genzyme does not offer increased dosing to U.S. patients because there is no threat of loss of market share in the U.S. market since Replagal® is not approved for use in the U.S. for treatment of Fabry disease.

91. On October 22, 2010, the European Medical Agency ("EMA") issued a press release stating that "The [European Medicines Agency's Committee for Medicinal Products for Human Use] CHMP is now recommending that physicians switch back to prescribing the full dose of Fabrazyme® according to the authorised product information, depending on the availability of enzyme replacement therapy and the severity of the disease." See EMA recommendation for full dosage of Fabrazyme® for Fabry Patients attached hereto and incorporated herein as Exhibit F.

92. The EMA's recommendation was based on the observation "that since the introduction of a lower dose of Fabrazyme® in June 2009, there has been a steady increase in the number of reported adverse events, matching the increase in the number of patients on the lower dose. At first, most of the events were pain-related, soon followed by reports of events affecting the heart, the central nervous system and the kidneys." Id.

93. On November 16, 2010, the EMA publicly published a statistical study on the Fabrazyme® supply shortage in Europe, which showed that patients not only had a return of life threatening symptoms but also an accelerated course of deterioration on the lowered dose. See EMA study attached hereto and incorporated herein as Exhibit G.

94. The EMA found that "In the early stages of the shortage the main increases in AEs [adverse events] were related to pain/paresthesia events, while later on in the shortage period, the main increases were in serious cardiac events such as myocardial infarction, in serious nervous disorders such as stroke, and – possibly to a lesser extent – in renal disorders. There have been consistent reports of a higher percentage of patients reporting peripheral pain, abdominal pain and diarrhoea on a daily basis after 25 June 2009 (start of the shortage)." Id.

95. Genzyme participated in the EMA study as part of its administration of the "Fabry Registry," a database collecting information on all Fabry patients, and Genzyme was aware of the EMA's results.

96. Genzyme did not and has not informed U.S. doctors or patients of the results of the EMA study.

97. In August of 2010, Plaintiffs Joseph Carik, Anita Hochendoner, Anita Bova and Amber Britton requested that the NIH exercise its march-in rights under the Bayh-Dole Act to allow other manufacturers to enter the market to make Fabrazyme® under U.S. Patent No. 5,356,804.

98. On December 1, 2010, the NIH denied the petitioners' request stating that the three-year approval process for new manufacturers under FDA regulations render the Bayh-Dole remedy of march-in useless for alleviating drug shortages in a timely manner, despite the NIH recognition of the critical

health need of patients for the drug.

99. Due to Genzyme's most recent manufacturing failure announced on March 25, 2011, the NIH has re-opened the Fabrazyme® march-in case based on the new information regarding further manufacturing disruptions and shortages. The case is currently pending.

100. As a direct result of manufacturing disruptions, Genzyme is forcing patients to miss doses, which results in an increased risk and severity of acute adverse reactions due to inconsistent infusion schedules.

101. As a direct result of the Genzyme Rationing Plan and Genzyme's denial of access to drug, reduction of dose of drug, change in dosing schedules, and sale of adulterated drug, Fabry patients have either had a return of symptoms, accelerated disease development, injury, and otherwise preventable disease progression, or have died during the shortage.

COUNT I: NEGLIGENCE

ANITA HOCHENDONER, ANITA BOVA, JOSEPH M. CARIK, MICHAEL MASULA, DAVID ROBERTS, TOM OLSZEWSKI, KYLE WILLINK, TOM STANZIANO, RICKY LADD, STEVE NAMNATH, AMBER BRITTON, AND SHAWN BRITTON, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

102. Paragraphs 1 through 101 are incorporated hereunder as though fully set forth at length.

103. The injuries sustained by Plaintiffs were due to and were the direct and proximate result of the negligence, carelessness, and recklessness of Defendants Genzyme and Mt. Sinai generally, and under the following particulars:

a. in that Defendants failed to take reasonable steps to avoid and prevent viral contamination in the Genzyme Allston, MA plant;

b. in that Defendants failed to take reasonable steps to maintain inventories and capital sufficient to mitigate foreseeable manufacturing shortages;

c. in that Defendants failed to take reasonable steps to avoid and prevent contamination of Fabrazyme® vials with particulate steel, glass and rubber;

d. in that the Defendants unilaterally devised, implemented, and approved with knowledge and consent the Genzyme Rationing Plan, and otherwise reduced or consented to reducing the dose of Fabrazyme® or denied it entirely for treatment of Fabry patients;

e. in that Defendants sold Fabrazyme® vials contaminated with glass, rubber and steel particles;

f. in that the Defendants designed, implemented and consented to the Genzyme Rationing Plan despite a statutory duty to ensure that Fabrazyme® was made available to all U.S. citizens and at the required dose pursuant to the Bayh-Dole Act's prohibition against non-use or unreasonable use of publically funded inventions under 35 U.S.C § 200, specifically U.S. Patent No. 5,356,804;

g. in that the Defendants instructed and through knowledge and consent reduced the dose of Fabrazyme® to dangerous, sub-efficacious and unapproved levels;

h. in that the Defendants barred physicians from administering the prescribed and lawful recommended dose of Fabrazyme® in accordance with the indications of the product insert;

i. in that the Defendants failed to test or require the testing of the effects of reducing the dosage of Fabrazyme® to unapproved levels to treat Fabry disease;

j. in that the Defendants failed to provide adequate warnings, cautions and directions concerning the dangers and limitations of the reduced dosage of Fabrazyme®;

k. in that the Defendants failed to provide or require proper and adequate reserves of unadulterated Fabrazyme® in order to prevent or mitigate manufacturing errors;

l. in that the Defendants failed to provide or license a second source of manufacture for Fabrazyme® in order to prevent or mitigate life-threatening supply chain disruptions; and

m. in otherwise failing to exercise the care and caution that a reasonable, careful and prudent entity would have or should have exercised under the circumstances.

104. As a direct and proximate result of the negligence of Defendants, the Plaintiffs have sustained the following serious injuries, some or all which may be of a permanent nature:

a. renal injury;
b. cardiac injury;
c. neurological injury;
d. peripheral pain;
e. chronic abdominal pain and diarrhea;
f. impairment of vision;
g. impairment of hearing;
h. increased severity and likelihood of infusion reactions, and
i. premature death and other serious and permanent injuries.

105. As a direct and proximate result of the aforesaid injuries, Plaintiffs have been damaged as follows:

a. Plaintiffs have been and will be required to expend large sums of money for medical and surgical attention, medical and surgical supplies, medical and surgical appliances, and medicines;

b. Plaintiffs have suffered and will continue to suffer great pain, suffering, inconvenience, impairment of bodily function, and mental anguish;
c. Plaintiffs have been and will be deprived of earnings and earning capacity;
d. Plaintiffs have suffered loss of enjoyment of life;
e. Plaintiffs have died or suffered a reduced life expectancy; and
f. Plaintiffs' general health, strength and vitality have been impaired.

WHEREFORE, Plaintiffs Anita Hochendoner, Anita Bova, Joseph M. Carik, Michael Masula, David Roberts, Kyle Willink, Tom Stanziano, Ricky Ladd, Steve Namnath, Thomas Olszewski, Amber Britton, and Shawn Britton, individually and on behalf of all others similarly situated, demand judgment against Defendants, Genzyme Corporation and Mount Sinai School of Medicine of the City University of

New York, jointly and severally in an amount in excess of $75,000.00, together with costs of suit. JURY TRIAL DEMANDED.

COUNT II: NEGLIGENCE *per Se*

ANITA HOCHENDONER, ANITA BOVA, JOSEPH M. CARIK, MICHAEL MASULA, KYLE WILLINK, TOM STANZIANO, STEVE NAMNATH, DAVID ROBERTS, INDIVIDUALLY AND ON BEHALF OF ALL OTHER SIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

106. Paragraphs 1 through 105 are incorporated hereunder as though fully set forth at length.

107. Defendants Genzyme and Mt. Sinai are strictly liable to Plaintiffs as follows under the Food, Drug, and Cosmetics Act 21 USC §351(a-d) regarding adulterated products, 21 USC §352(f) regarding adequate warning and labeling, 21 USC §355(j) regarding the statutory approval process for testing of previously unapproved doses, and 21 USC §356a(a) regarding testing required for substantial manufacturing changes; as well as being strictly liable under the Bayh-Dole Act 35 USC §200 regarding the prohibition of unreasonable use or non-use of Bayh-Dole regulated inventions which are necessary for human health:

a. for restricting and consenting to restriction of administering Fabrazyme® at a dose that is below the FDA approved use of 1 mg/kg body weight infused every two weeks;
b. in that the Defendants barred physicians from administering the prescribed and lawful recommended dose of Fabrazyme® in accordance with the indications of the product insert;
c. for failing to seek FDA approval for using the reduced dosage to treat Fabry disease;
d. for selling Fabrazyme® contaminated with glass, rubber and steel particles;
e. for failure to give adequate and complete warnings of the known or knowable dangers involved in the use Fabrazyme® at a reduced dose as required by FDA regulations;

f. for unreasonably using a publicly funded invention by restricting administration to below the FDA approved dose and for non-use of the invention by banning the publicly funded invention from being given to newly diagnosed Fabry patients;

g. for failing to provide or require proper and adequate reserves of unadulterated Fabrazyme® in order to prevent or mitigate manufacturing errors;

h. for failing to provide or license a second source of manufacture for Fabrazyme® in order to prevent or mitigate life-threatening supply chain disruptions; and

i. in otherwise failing to exercise the care and caution that a reasonable, careful and prudent entity would have or should have exercised under the circumstances.

108. By virtue of the negligence *per se* of Defendants, Defendants are liable for the severe injuries and conditions as set forth herein in Count I of Plaintiffs Anita Hochendoner, Anita Bova, Kyle Willink, Steve Namnath, Joseph M. Carik, Michael Masula, Tom Stanziano, David Roberts, and all others similarly situated.

109. As a direct and proximate result of the aforesaid injuries, Plaintiffs Anita Hochendoner, Anita Bova, Kyle Willink, Joseph M. Carik, Michael Masula, Tom Stanziano, Steve Namnath, David Roberts, and all others similarly situated have suffered damages as set forth herein in Count I.

WHEREFORE, Plaintiffs Anita Hochendoner, Anita Bova, Kyle Willink, Joseph M. Carik, Michael Masula, Tom Stanziano, Steve Namnath, and David Roberts, individually and on behalf of all others similarly situated, demand judgment against Defendants Genzyme Corporation and Mount Sinai School of Medicine of the City University of New York, jointly and severally in an amount in excess of $75,000.00, together with costs of suit. JURY TRIAL DEMANDED.

COUNT III: STRICT LIABILITY

ANITA HOCHENDONER, ANITA BOVA, MICHAEL MASULA, TOM STANZIANO, STEVE NAMNATH, KYLE WILLINK, AND JOSEPH M. CARIK, INDIVIDUALLY AND ON BEHALF OF ALL OTHER SIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

110. Paragraphs 1 through 109 are incorporated hereunder as though fully set forth at length.

111. Defendants Genzyme and Mt. Sinai are strictly liable to Plaintiffs as follows:

a. for failure to adequately and safely label the reduced dosage of Fabrazyme®;
b. for selling and licensing the use of Fabrazyme® at a defective dose;
c. for selling Fabrazyme® in a defective condition being adulterated with glass, rubber and steel particles;
d. for selling and licensing the use of Fabrazyme® at a reduced dose when the dose is untested and unreasonably dangerous for its intended use; and
e. for failure to give adequate and complete warnings of the known or knowable dangers involved in the use Fabrazyme® at a reduced dose.

112. By virtue of the strict liability of Defendants, Defendants are liable for the severe injuries and conditions as set forth herein in Count I of Plaintiffs Anita Hochendoner, Anita Bova, Kyle Willink, Steve Namnath, Joseph M. Carik, Michael Masula, Tom Stanziano, and all others similarly situated.

113. As a direct and proximate result of the aforesaid injuries, Plaintiffs Anita Hochendoner, Anita Bova, Kyle Willink, Steve Namnath, Joseph M. Carik, Michael Masula, Tom Stanziano, and all others similarly situated have suffered damages as set forth herein in Count I.

WHEREFORE, Plaintiffs Anita Hochendoner, Anita Bova, Kyle Willink, Steve Namnath, Joseph M. Carik, Michael Masula, Tom Stanziano, individually and on behalf of all others similarly situated, demand judgment against Defendants Genzyme Corporation and Mount Sinai School of Medicine of the

City University of New York, jointly and severally in an amount in excess of $75,000.00, together with costs of suit. JURY TRIAL DEMANDED.

COUNT IV: BREACH OF WARRANTY

ANITA HOCHENDONER, ANITA BOVA, JOSEPH M. CARIK, MICHAEL MASULA, KYLE WILLINK, STEVE NAMNATH, RICKY LADD, TOM STANZIANO, DAVID ROBERTS, TOM OLSZEWSKI, AMBER BRITTON, AND SHAWN BRITTON, INDIVIDUALLY AND ON BEHALF OF ALL OTHER SIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

114. Paragraphs 1 through 113 are incorporated hereunder as though fully set forth at length.

115. All of the resultant losses, damages and injuries sustained by Plaintiffs resulted directly and proximately from Defendants Genzyme's and Mt. Sinai's breach of express and implied warranties of merchantability or fitness for the use of Fabrazyme®, in the following particulars:

a. Defendants expressly warranted in the Fabrazyme® product insert that Fabrazyme® reduces globotriacylceramide deposition in capillary endothelium of the kidney and certain other cell types, despite never having tested whether the product and inconsistent dosing reduces such deposition;

b. Defendants expressly warranted in the Fabrazyme® product insert that Fabrazyme® is indicated for use to treat Fabry disease, despite never having obtained FDA approval for using lowered dose for such an indication;

c. the Defendants failed to adequately, properly, and timely test the reduced dose prior to use;

d. Fabrazyme®, given at reduced dosage and being adulterated with glass, steel, and rubber particles, is not fit for the ordinary purpose for which it is customarily or foreseeably used;

e. the Defendants knew or should have known that the adulterated drug and reduced dosage of Fabrazyme® is dangerous and likely to cause damage to users;

f. Fabrazyme®, given at reduced dosage and being adulterated, was not of merchantable

quality and was not in conformity, insofar as safety is concerned, with products used in a normal course of business as well as statutory mandates;

g. the Defendants knew or should have known that in order to make Fabrazyme® effective for its intended use, they should have provided the drug at the recommended dose;

h. the Defendants knew or should have known, that due to the inherently dangerous nature of the design of the dosing schedule as well as the drug adulteration, they should have provided warnings on the product to protect users;

i. the Defendants did not keep abreast of the state of the art in the science and knew of adverse events involving reduced dosage and failed to warn users;

j. the Defendants did not disclose to the users of the reduced dosage of Fabrazyme® that the dosing was defectively and unreasonably designed, thereby making the product dangerous to use;

k. the Defendants included an incorrect and unapproved product insert because Defendants do not allow physicians to treat patients with the recommended dose for which the insert was intended;

l. the Defendants knew or should have known that users were relying upon the expertise of the Defendants in designing, fabricating, manufacture, labeling as well as supplying Fabrazyme®;

m. in expressly and impliedly warranting that a lowered dose of Fabrazyme® was approved for use by the FDA and efficacious for use in the treatment of Fabry disease;

n. in expressly and impliedly misrepresenting that a lowered dose of Fabrazyme® was approved for by the FDA and efficacious for use in the treatment of Fabry disease; and

o. in expressly and impliedly misrepresenting that a lowered dose of Fabrazyme® was approved for by the FDA and efficacious for use in the treatment of Fabry disease.

116. As a direct and proximate cause of the breach of these expressed or implied warranties, Plaintiffs Anita Hochendoner, Anita Bova, Kyle Willink, Joseph M. Carik, Michael Masula, Tom Stanziano, Steve Namnath, Ricky Ladd, David Roberts, Thomas Olszewski, Amber Britton, Shawn Britton, and all others similarly situated suffered severe injuries and conditions as set forth

herein in Count I.

117. As a result of their injuries and conditions, Plaintiffs Anita Hochendoner, Anita Bova, Kyle Willink, Joseph M. Carik, Michael Masula, Tom Stanziano, Steve Namnath, Ricky Ladd, David Roberts, Thomas Olszewski, Amber Britton, Shawn Britton, and all others similarly situated have suffered damages as set forth herein in Count I.

WHEREFORE, Plaintiffs Anita Hochendoner, Anita Bova, Kyle Willink, Joseph M. Carik, Michael Masula, Tom Stanziano, Steve Namnath, Ricky Ladd, David Roberts, Thomas Olszewski, Amber Britton, Shawn Britton, individually and on behalf of all others similarly situated, demand judgment against Defendants Genzyme Corporation and Mount Sinai School of Medicine of the City University of New York, jointly and severally in an amount in excess of $75,000.00, together with costs of suit. JURY TRIAL DEMANDED.

COUNT V: VIOLATION OF BAYH-DOLE ACT PROSCRIPTION OF NON-USE OR UNREASONABLE USE OF PUBLICALLY FUNDED INVENTIONS (IMPLIED CAUSE OF ACTION)

ANITA HOCHENDONER, ANITA BOVA, JOSEPH M. CARIK, MICHAEL MASULA, DAVID ROBERTS, TOM STANZIANO, KYLE WILLINK, STEVE NAMNATH, RICKY LADD, TOM OLSZEWSKI, AMBER BRITTON, AND SHAWN BRITTON, INDIVIDUALLY AND ON BEHALF OF ALL OTHER SIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

118. Paragraphs 1 through 117 are incorporated hereunder as though fully set forth at length.

119. The injuries sustained by Plaintiffs were due to Defendants Genzyme and Mt. Sinai violating the Bayh-Dole Act 35 U.S.C. §200, generally and under the following particulars:

a. in that the Defendants reduced the dose of Fabrazyme® or denied it entirely for Plaintiffs'

Fabry disease thereby unreasonably using and engaging in non-use of the publicly-funded invention, U.S. Patent No. 5,356,804;

b. in that the Defendants instituted the drug ban for some citizens and rationing to other citizens despite a statutory duty to ensure that Fabrazyme® was made available to U.S. citizens and at the required dose pursuant to the Bayh-Dole Act's specific prohibition against a contractor's non-use and unreasonable use of publically funded invention under 35 U.S.C. §200;

c. in that the Defendants failed to require or provide adequate safeguards to prevent or mitigate damages resulting from the unreasonable use and non-use of publicly-funded invention, U.S. Patent No. 5,356,804;

d. in that the Defendants instituted the rationing and denial of access despite lacking title or other property right to any patent right of non-use or unreasonable use that otherwise may be allowed under 35 U.S.C. § 271(d)(4);

e. in that the Defendants willfully barred physicians from administering the prescribed and lawful recommended dose of the invention Fabrazyme®; and

f. in that the Defendants caused special injuries unique to the protected class created under the language of 35 U.S.C. §200, whereby such injuries directly arise out of the non-use and unreasonable use of the invention because the Plaintiffs have Fabry disease and rely on access to the publicly funded invention, Fabrazyme®, specifically to treat their disease, which is otherwise fatal.

120. By virtue of the violation of the Bayh-Dole Act, Defendants are liable for the severe injuries and conditions of Plaintiffs Anita Hochendoner, Anita Bova, Kyle Willink, Joseph M. Carik, Michael Masula, Tom Stanziano, Steve Namnath, Ricky Ladd, David Roberts, Thomas Olszewski, Amber Britton, Shawn Britton, and all others similarly situated as set forth herein in Count I.

121. As a result of their injuries and conditions, Plaintiffs Anita Hochendoner, Anita Bova, Kyle Willink, Joseph M. Carik, Michael Masula, Tom Stanziano, Steve Namnath, Ricky Ladd, David

Roberts, Thomas Olszewski, Amber Britton, Shawn Britton, and all others similarly situated have suffered damages as set forth herein in Count I.

WHEREFORE, Plaintiffs Anita Hochendoner, Anita Bova, Kyle Willink, Joseph M. Carik, Michael Masula, Tom Stanziano, Steve Namnath, Ricky Ladd, David Roberts, Thomas Olszewski, Amber Britton, Shawn Britton, individually and on behalf of all others similarly situated, demand judgment against Defendants Genzyme Corporation and Mount Sinai School of Medicine of the City University of New York, jointly and severally in an amount in excess of $75,000.00, together with costs of suit. JURY TRIAL DEMANDED.

COUNT VI: PENNSYLVANIA UNFAIR TRADE PRACTICES CONSUMER PROTECTION LAW VIOLATION (73 P.S. §§201-1 - 201-9.2)
ANITA HOCHENDONER, ANITA BOVA, AND MICHAEL MASULA, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

122. Paragraphs 1 through 121 are incorporated hereunder as though fully set forth at length.

123. All of the losses, damages and injuries sustained by Plaintiffs resulted directly and proximately from Defendants Genzyme's and Mt. Sinai's deceptive acts or practices regarding the sale and use of Fabrazyme®, generally, and in the following particulars:

a. in failing to inform the Plaintiff that the dosage given was unapproved and unauthorized and the possible consequences of such unapproved and unauthorized use;
b. in affirmatively representing that the drug given at reduced dosage and, further, contaminated with glass, rubber and steel particles is approved to successfully treat Fabry disease and Fabry disease patients will benefit from such use;
c. in willfully including an incorrect and unapproved product insert that does not apply to a reduced dosage;

d. in barring physicians from administering the prescribed and lawful recommended dose of Fabrazyme® in accordance with the indications of the product insert; and

e. in expressly or impliedly misrepresenting that the reduced dose and further that the adulterated Fabrazyme® was in accordance with statutory mandates and efficacious for use.

124. By the use of deceptive trade practices, Defendants are liable for the severe injuries and conditions of Plaintiffs Anita Hochendoner, Anita Bova, Michael Masula, and all others similarly situated, as set forth herein in Count I.

125. As a direct and proximate result of the aforesaid injuries, Anita Hochendoner, Anita Bova, Michael Masula, and all others similarly situated, have suffered damages as set forth herein in Count I.

WHEREFORE, Plaintiffs Anita Hochendoner, Anita Bova, Michael Masula, individually and on behalf of all others similarly situated, demand judgment against Defendants Genzyme Corporation and Mount Sinai School of Medicine of the City University of New York, jointly and severally in an amount in excess of $75,000.00, together with treble damages and costs of suit. JURY TRIAL DEMANDED.

COUNT VII: NEVADA STATE LAW DECEPTIVE TRADE PRACTICE VIOLATION (NEVADA REVISED STATUTES §§ 598.0903-0990)
JOSEPH M. CARIK INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

126. Paragraphs 1 through 125 are incorporated hereunder as though fully set forth at length.

127. All of the resultant losses, damages and injuries sustained by Plaintiff resulted directly and proximately from Defendants Genzyme's and Mt. Sinai's deceptive acts or practices regarding the

sale and use of the drug, Fabrazyme®, generally, and in the following particulars:

a. in failing to inform the Plaintiff that the dosage given was unapproved and unauthorized and the possible consequences of such unapproved and unauthorized use;

b. in affirmatively representing that the drug given at reduced dosage and contaminated with glass, rubber and steel particles is approved to successfully treat Fabry disease and Fabry disease patients will benefit from such use;

c. in willfully including an incorrect and unapproved product insert that does not apply to a reduced dosage;

d. in barring physicians from administering the prescribed and lawful recommended dose of Fabrazyme® in accordance with the indications of the product insert; and

e. in expressly or impliedly misrepresenting that the reduced dose and, further that the adulterated Fabrazyme® was in accordance with statutory mandates and efficacious for use.

128. By the use of deceptive trade practices, Defendants are liable for the severe injuries and conditions of Plaintiff Joseph M. Carik, and all others similarly situated, as set forth herein in Count I.

129. As a direct and proximate result of the aforesaid injuries, Joseph M. Carik, and all others similarly situated, have suffered damages as set forth herein in Count I.

WHEREFORE, Plaintiff Joseph M. Carik demands judgment against Defendants Genzyme Corporation and Mount Sinai School of Medicine of the City University of New York, jointly and severally in an amount in excess of $75,000.00, together with punitive damages, and costs of suit. JURY TRIAL DEMANDED.

COUNT VIII: MICHIGAN STATE LAW DECEPTIVE TRADE PRACTICE VIOLATION (MICHIGAN COMPILED LAWS § 445.903 *et seq.)*
THOMAS OLSZEWSKI, RICKY LADD, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

130. Paragraphs 1 through 129 are incorporated hereunder as though fully set forth at length.

131. All of the resultant losses, damages and injuries sustained by Plaintiff resulted directly and proximately from Defendants Genzyme's and Mt. Sinai's deceptive acts or practices regarding the sale and use of the drug, Fabrazyme®, generally, and in the following particulars:

a. in failing to inform the Plaintiff that the dosage given was unapproved and unauthorized and the possible consequences of such unapproved and unauthorized use;
b. in affirmatively representing that the drug given at reduced dosage and further contaminated with glass, rubber and steel particles is approved to successfully treat Fabry disease and Fabry disease patients will benefit from such use;
c. in willfully including an incorrect and unapproved product insert that does not apply to a reduced dosage;
d. in barring physicians from administering the prescribed and lawful recommended dose of Fabrazyme® in accordance with the indications of the product insert; and
e. in expressly or impliedly misrepresenting that the reduced dose and further that the adulterated Fabrazyme® was in accordance with statutory mandates and efficacious for use.

132. By the use of deceptive trade practices, Defendants are liable for the severe injuries and conditions of Plaintiffs Thomas Olzewski, Ricky Ladd, and all others similarly situated, as set forth herein in Count I.

133. As a direct and proximate result of the aforesaid injuries, Thomas Olzewski, Ricky Ladd, and all others similarly situated, have suffered damages as set forth herein in Count I.

WHEREFORE, Plaintiff Thomas Olszewski and Ricky Ladd demand judgment against Defendants

Genzyme Corporation and Mount Sinai School of Medicine of the City University of New York, jointly and severally in an amount in excess of $75,000.00, together with treble damages and costs of suit. JURY TRIAL DEMANDED.

COUNT IX: DELAWARE UNIFORM DECEPTIVE TRADE PRACTICES ACT (D.C. 6 § 2532 *et seq*.)
KYLE WILLINK, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

134. Paragraphs 1 through 133 are incorporated hereunder as though fully set forth at length.

135. All of the resultant losses, damages and injuries sustained by Plaintiff resulted directly and proximately from Defendants Genzyme's and Mt. Sinai's deceptive acts or practices regarding the sale and use of the drug, Fabrazyme®, generally, and in the following particulars:

a. in failing to inform the Plaintiff that the dosage given was unapproved and unauthorized and the possible consequences of such unapproved and unauthorized use;
b. in affirmatively representing that the drug given at reduced dosage and further contaminated with glass, rubber and steel particles is approved to successfully treat Fabry disease and Fabry disease patients will benefit from such use;
c. in willfully including an incorrect and unapproved product insert that does not apply to a reduced dosage;
d. in barring physicians from administering the prescribed and lawful recommended dose of Fabrazyme® in accordance with the indications of the product insert; and
e. in expressly or impliedly misrepresenting that the reduced dose and adulterated Fabrazyme® was in accordance with statutory mandates and efficacious for use.

136. By the use of deceptive trade practices, Defendants are liable for the severe injuries and conditions of Plaintiff Kyle Willink, and all others similarly situated, as set forth herein in Count I.

137. As a direct and proximate result of the aforesaid injuries, Kyle Willink, and all others similarly situated, have suffered damages as set forth herein in Count I.

WHEREFORE, Plaintiff Kyle Willink demands judgment against Defendants Genzyme Corporation and Mount Sinai School of Medicine of the City University of New York, jointly and severally in an amount in excess of $75,000.00, together with treble damages and costs of suit. JURY TRIAL DEMANDED.

COUNT X: NORTH CAROLINA UNFAIR AND DECEPTIVE TRADE PRACTICES ACT VIOLATION (N.C.G.S. § 75-1.1 *et seq.*)

DAVID ROBERTS, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

138. Paragraphs 1 through 137 are incorporated hereunder as though fully set forth at length.

139. All of the resultant losses, damages and injuries sustained by Plaintiff resulted directly and proximately from Defendants Genzyme's and Mt. Sinai's deceptive acts or practices regarding the sale and use of the drug, Fabrazyme®, generally, and in the following particulars:

a. in failing to inform the Plaintiff that the dosage given was unapproved and unauthorized and the possible consequences of such unapproved and unauthorized use;
b. in affirmatively representing that the drug given at reduced dosage and further contaminated with glass, rubber and steel particles is approved to successfully treat Fabry disease and Fabry disease patients will benefit from such use;
c. in willfully including an incorrect and unapproved product insert that does not apply to a reduced dosage;
d. in barring physicians from administering the prescribed and lawful recommended dose of Fabrazyme® in accordance with the indications of the product insert; and
e. in expressly or impliedly misrepresenting that the reduced dose and adulterated Fabrazyme® was in accordance with statutory mandates and efficacious for use.

140. By the use of deceptive trade practices, Defendants are liable for the severe injuries and conditions of Plaintiff David Roberts, and all others similarly situated, as set forth herein in Count I.

141. As a direct and proximate result of the aforesaid injuries, David Roberts, and all others similarly situated, have suffered damages as set forth herein in Count I.

WHEREFORE, Plaintiff David Roberts demands judgment against Defendants Genzyme Corporation and Mount Sinai School of Medicine of the City University of New York, jointly and severally in an amount in excess of $75,000.00, together with treble damages and costs of suit. JURY TRIAL DEMANDED.

COUNT XI: FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT VIOLATION (F.S. § 501.201 *et seq.*)
TOM STANZIANO, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

142. Paragraphs 1 through 141 are incorporated hereunder as though fully set forth at length.

143. All of the resultant losses, damages and injuries sustained by Plaintiff resulted directly and proximately from Defendants Genzyme's and Mt. Sinai's deceptive acts or practices regarding the sale and use of the drug, Fabrazyme®, generally, and in the following particulars:

a. in failing to inform the Plaintiff that the dosage given was unapproved and unauthorized and the possible consequences of such unapproved and unauthorized use;
b. in affirmatively representing that the drug given at reduced dosage and further contaminated with glass, rubber and steel particles is approved to successfully treat Fabry disease and Fabry disease patients will benefit from such use;
c. in willfully including an incorrect and unapproved product insert that does not apply to a

reduced dosage;

d. in barring physicians from administering the prescribed and lawful recommended dose of Fabrazyme® ® in accordance with the indications of the product insert; and

e. in expressly or impliedly misrepresenting that the reduced dose and adulterated Fabrazyme® was in accordance with statutory mandates and efficacious for use.

144. By the use of deceptive trade practices, Defendants are liable for the severe injuries and conditions of Plaintiff Tom Stanziano, and all others similarly situated, as set forth herein in Count I.

145. As a direct and proximate result of the aforesaid injuries, Tom Stanziano, and all others similarly situated, have suffered damages as set forth herein in Count I.

WHEREFORE, Plaintiff Tom Stanziano demands judgment against Defendants Genzyme Corporation and Mount Sinai School of Medicine of the City University of New York, jointly and severally in an amount in excess of $75,000.00, together with costs of suit. JURY TRIAL DEMANDED.

COUNT XII: WASHINGTON UNIFORM DECEPTIVE TRADE PRACTICES ACT VIOLATION (RCW § 19.86.010 *et seq.*)
AMBER BRITTON AND SHAWN BRITTON, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

146. Paragraphs 1 through 145 are incorporated hereunder as though fully set forth at length.

147. All of the resultant losses, damages and injuries sustained by Plaintiffs resulted directly and proximately from Defendants Genzyme's and Mt. Sinai's deceptive acts or practices regarding the sale and use of Fabrazyme®, generally, and in the following particulars:

a. in failing to inform the Plaintiff that the dosage given was unapproved and unauthorized and the possible consequences of such unapproved and unauthorized use;

b. in affirmatively representing that the drug given at reduced dosage and, further, contaminated with glass, rubber and steel particles is approved to successfully treat Fabry disease and Fabry disease patients will benefit from such use;

c. in willfully including an incorrect and unapproved product insert that does not apply to a reduced dosage;

d. in barring physicians from administering the prescribed and lawful recommended dose of Fabrazyme® in accordance with the indications of the product insert; and

e. in expressly or impliedly misrepresenting that the reduced dose and further that the adulterated Fabrazyme® was in accordance with statutory mandates and efficacious for use.

148. By the use of deceptive trade practices, Defendants are liable for the severe injuries and conditions of Plaintiffs Amber Britton, Shawn Britton, and all others similarly situated, as set forth herein in Count I.

149. As a direct and proximate result of the aforesaid injuries, Amber Britton, Shawn Britton, and all others similarly situated, have suffered damages as set forth herein in Count I.

WHEREFORE, Plaintiffs Amber Britton and Shawn Britton, individually and on behalf of all others similarly situated, demand judgment against Defendants Genzyme Corporation and Mount Sinai School of Medicine of the City University of New York, jointly and severally in an amount in excess of $75,000.00, together with treble damages and costs of suit. JURY TRIAL DEMANDED.

COUNT XIII: WASHINGTON PRODUCT LIABILITY ACT VIOLATION
(R.C.W. § 7.72 *et seq.*)
AMBER BRITTON AND SHAWN BRITTON, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

150. Paragraphs 1 through 149 are incorporated hereunder as though fully set forth at length.

151. All of the resultant losses, damages and injuries sustained by Plaintiff resulted directly and proximately from Defendant Genzyme's practices regarding the manufacture, sale and use of the drug, Fabrazyme®, generally, and in the following particulars:

a. in that the Defendant failed to take reasonable steps to avoid and prevent viral contamination in the Genzyme Allston, MA plant;
b. in that the Defendant failed to take reasonable steps to maintain inventories and capital sufficient to mitigate foreseeable manufacturing shortages;
c. in that the Defendant failed to take reasonable steps to avoid and prevent contamination of Fabrazyme® vials with particulate steel, glass and rubber;
d. in that the Defendant manufactured and sold defective Fabrazyme® vials contaminated with glass, rubber and steel particles;
e. in that the Defendant unilaterally devised, and willfully implemented, the Genzyme Rationing Plan, and otherwise reduced the dose of Fabrazyme® or denied it entirely for treatment of Fabry patients despite physician's prescribing a lawful and approved dose;
f. in that the Defendant designed and implemented the Genzyme Rationing Plan despite a statutory duty to ensure that Fabrazyme® was made available to all U.S. citizens and at the required dose pursuant to the Bayh-Dole Act's prohibition against non-use or unreasonable use of publically funded inventions under 35 U.S.C § 200, specifically U.S. Patent No. 5,356,804;
g. in that the Defendant instructed physicians and patients to use a reduced the dose of Fabrazyme® that was dangerous, sub-efficacious and unapproved;
h. in that the Defendant barred physicians from administering the prescribed and lawful recommended dose of Fabrazyme® in accordance with the indications of the product insert;
i. in that the Defendant failed to test or require the testing of the effects of reducing the

dosage of Fabrazyme® to unapproved levels to treat Fabry disease;

j. in that the Defendant failed to provide adequate warnings, cautions and directions concerning the dangers and limitations of the reduced dosage of Fabrazyme®;

k. in that the Defendant failed to provide or require proper and adequate reserves of unadulterated Fabrazyme® in order to prevent or mitigate manufacturing errors;

l. in that the Defendant failed to provide or license a second source of manufacture for Fabrazyme® in order to prevent or mitigate life-threatening supply chain disruptions;

m. in that the Defendant failed to inform the Plaintiffs that the dosage given was unapproved and unauthorized as well as the possible consequences of such unapproved and unauthorized use;

n. in that the Defendant affirmatively represented that the drug given at reduced dosage and further contaminated with glass, rubber and steel particles is approved to successfully treat Fabry disease and Fabry disease patients will benefit from such use;

o. in that the Defendant expressly or impliedly misrepresented that the reduced dose and adulterated Fabrazyme® was in accordance with statutory mandates and efficacious for use;

p. in that the Defendant expressly warranted in the Fabrazyme® product insert that Fabrazyme® reduces globotriacylceramide deposition in capillary endothelium of the kidney and certain other cell types, despite never having tested whether the product at the lower dose and at inconsistent dosing reduces such deposition;

q. in that the Defendant expressly warranted in the Fabrazyme® product insert that Fabrazyme® is indicated for use to treat Fabry disease, despite never having obtained FDA approval for using lowered dose for such an indication;

r. in that the Defendant failed to adequately, properly, and timely test the reduced dose prior to use;

s. in that the Defendant manufactured and sold Fabrazyme®, given at reduced dosage and further being adulterated with glass, steel, and rubber particles, which is not fit for the ordinary purpose for which it is customarily or foreseeably used;

t. in that the Defendant knew or should have known that the adulterated drug and reduced dosage of Fabrazyme® is dangerous and likely to cause damage to users;

u. in that the Defendant manufactured and sold Fabrazyme®, given at reduced dosage and further being adulterated, which was not of merchantable quality and was not in conformity, insofar as safety is concerned, with products used in a normal course of business as well as statutory mandates;

v. in that the Defendant knew or should have known that in order to make Fabrazyme® effective for its intended use, it should have provided the drug at the recommended dose;

w. in that the Defendant knew or should have known, that due to the inherently dangerous nature of the design of the dosing schedule as well as the drug adulteration, it should have provided warnings on the product to protect users;

x. in that the Defendant did not keep abreast of the state of the art in the science and knew of adverse events involving reduced dosage and failed to warn physicians and users;

y. in that the Defendant did not disclose to the physicians and users that the dosing was defectively and unreasonably designed, thereby making the product dangerous to use;

z. in that the Defendant willfully included an incorrect and unapproved product insert that does not apply to a reduced dosage;

aa. in that the Defendant knew or should have known that physicians and users were relying upon the expertise of the Defendant in designing, fabricating, manufacture, labeling as well as supplying Fabrazyme®;

bb. in that the Defendant expressly and impliedly warranted that a lowered dose of Fabrazyme® was approved for use by the FDA and efficacious for use in the treatment of Fabry disease; and

cc. in otherwise failing to exercise the care and caution that a reasonable, careful and prudent entity would have or should have exercised under the circumstances.

152. By its actions, Defendants are liable for the severe injuries and conditions of Plaintiffs Amber Britton, Shawn Britton, and all others similarly situated, as set forth herein in Count I.

153. As a direct and proximate result of the aforesaid injuries, Plaintiffs Amber Britton, Shawn Britton, and all others similarly situated, have suffered damages as set forth herein in Count I.

WHEREFORE, Plaintiffs Amber Britton and Shawn Britton demand judgment against Defendants Genzyme Corporation in an amount in excess of $75,000.00, together with punitive damages, and costs of suit. JURY TRIAL DEMANDED.

COUNT XIV: MICHIGAN STATE PRODUCT LIABILITY ACT VIOLATION (M.C.L. 600.2946 *et seq.*)
THOMAS OLSZEWSKI AND RICKY LADD, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

154. Paragraphs 1 through 153 are incorporated hereunder as though fully set forth at length.

155. All of the resultant losses, damages and injuries sustained by Plaintiff resulted directly and proximately from Defendant Genzyme's practices regarding the manufacture, sale and use of the drug, Fabrazyme®, generally, and in the following particulars:

a. in that the Defendant failed to take reasonable steps to avoid and prevent viral contamination in the Genzyme Allston, MA plant;
b. in that the Defendant failed to take reasonable steps to maintain inventories and production capital sufficient to mitigate foreseeable manufacturing shortages;
c. in that the Defendant failed to take reasonable steps to avoid and prevent contamination of Fabrazyme® vials with particulate steel, glass and rubber;
d. in that the Defendant manufactured and sold defective Fabrazyme® vials contaminated with glass, rubber and steel particles;
e. in that the Defendant unilaterally devised, and willfully implemented, the Genzyme Rationing Plan, and otherwise reduced the dose of Fabrazyme® or denied it entirely for treatment of Fabry patients despite physician's prescribing a lawful and approved dose;
f. in that the Defendant designed and implemented the Genzyme Rationing Plan despite a statutory duty to ensure that Fabrazyme® was made available to all U.S. citizens and at the required dose pursuant to the Bayh-Dole Act's prohibition against non-use or unreasonable use of publically funded inventions under 35 U.S.C § 200, specifically U.S. Patent No. 5,356,804;
g. in that the Defendant instructed physicians and patients to use a reduced the dose of Fabrazyme® that was dangerous, sub-efficacious and unapproved;
h. in that the Defendant barred physicians from administering the prescribed and lawful recommended dose of Fabrazyme® in accordance with the indications of the product insert;
i. in that the Defendant failed to test or require the testing of the effects of reducing the

dosage of Fabrazyme® to unapproved levels to treat Fabry disease;

j. in that the Defendant failed to provide adequate warnings, cautions and directions concerning the dangers and limitations of the reduced dosage of Fabrazyme®;

k. in that the Defendant failed to provide or require proper and adequate reserves of unadulterated Fabrazyme® in order to prevent or mitigate manufacturing errors;

l. in that the Defendant failed to provide or license a second source of manufacture for Fabrazyme® in order to prevent or mitigate life-threatening supply chain disruptions;

m. in that the Defendant failed to inform the Plaintiffs that the dosage given was unapproved and unauthorized as well as the possible consequences of such unapproved and unauthorized use;

n. in that the Defendant affirmatively represented that the drug given at reduced dosage and further contaminated with glass, rubber and steel particles is approved to successfully treat Fabry disease and Fabry disease patients will benefit from such use;

o. in that the Defendant expressly or impliedly misrepresented that the reduced dose and adulterated Fabrazyme® was in accordance with statutory mandates and efficacious for use;

p. in that the Defendant expressly warranted in the Fabrazyme® product insert that Fabrazyme® reduces globotriacylceramide deposition in capillary endothelium of the kidney and certain other cell types, despite never having tested whether the product at the lowered dose and inconsistent dosing reduces such deposition;

q. in that the Defendant expressly warranted in the Fabrazyme® product insert that Fabrazyme® is indicated for use to treat Fabry disease, despite never having obtained FDA approval for using a lowered dose for such an indication;

r. in that the Defendant failed to adequately, properly, and timely test the reduced dose prior to use;

s. in that the Defendant manufactured and sold Fabrazyme®, given at reduced dosage and further being adulterated with glass, steel, and rubber particles, which is not fit for the ordinary purpose for which it is customarily or foreseeably used;

t. in that the Defendant knew or should have known that the adulterated drug and reduced dosage of Fabrazyme® is dangerous and likely to cause damage to users;

u. in that the Defendant manufactured and sold Fabrazyme®, given at reduced dosage and further being adulterated, which was not of merchantable quality and was not in conformity, insofar as safety is concerned, with products used in a normal course of business as well as statutory mandates;

v. in that the Defendant knew or should have known that in order to make Fabrazyme® effective for its intended use, it should have provided the drug at the recommended dose;

w. in that the Defendant knew or should have known, that due to the inherently dangerous nature of the design of the dosing schedule as well as the drug adulteration, it should have provided warnings on the product to protect users;

x. in that the Defendant did not keep abreast of the state of the art in the science and knew of adverse events involving reduced dosage and failed to warn physicians and users;

y. in that the Defendant did not disclose to the physicians and users that the dosing was defectively and unreasonably designed, thereby making the product dangerous to use;

z. in that the Defendant willfully included an incorrect and unapproved product insert that does not apply to a reduced dosage;

aa. in that the Defendant knew or should have known that physicians and users were relying upon the expertise of the Defendant in designing, fabricating, manufacture, labeling as well as supplying Fabrazyme®;

bb. in that the Defendant expressly and impliedly warranted that a lowered dose of Fabrazyme® was approved for use by the FDA and efficacious for use in the treatment of Fabry disease; and

cc. in otherwise failing to exercise the care and caution that a reasonable, careful and prudent entity would have or should have exercised under the circumstances.

156. By its actions, Defendants are liable for the severe injuries and conditions of Plaintiffs Thomas Olszewski, Ricky Ladd, and all others similarly situated, as set forth herein in Count I.

157. As a direct and proximate result of the aforesaid injuries, Plaintiffs Thomas Olszewski, Ricky Ladd, and all others similarly situated have suffered damages as set forth herein in Count I.

WHEREFORE, Plaintiffs Thomas Olszewski and Ricky Ladd demand judgment against Defendants Genzyme Corporation in an amount in excess of $75,000.00, together with punitive damages, and costs of suit. JURY TRIAL DEMANDED.

COUNT XV: CALIFORNIA BUSINESS AND PROFESSIONAL CODE VIOLATION (CAL. BPC CODE § 17200 *et seq.*)
STEVE NAMNATH, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

158. Paragraphs 1 through 157 are incorporated hereunder as though fully set forth at length.

159. All of the resultant losses, damages and injuries sustained by Plaintiffs resulted directly and proximately from Defendants Genzyme's and Mt. Sinai's unfair trade acts or practices regarding the sale and use of Fabrazyme®, generally, and in the following particulars:

a. in failing to inform the Plaintiff that the dosage given was unapproved and unauthorized and the possible consequences of such unapproved and unauthorized use;
b. in affirmatively representing that the drug given at reduced dosage and, further, contaminated with glass, rubber and steel particles is approved to successfully treat Fabry disease and Fabry disease patients will benefit from such use;
c. in willfully including an incorrect and unapproved product insert that does not apply to a reduced dosage;
d. in barring physicians from administering the prescribed and lawful recommended dose of Fabrazyme® in accordance with the indications of the product insert; and
e. in expressly or impliedly misrepresenting that the reduced dose and further that the adulterated Fabrazyme® was in accordance with statutory mandates and efficacious for use.

160. By the use of deceptive trade practices, Defendants are liable for the severe injuries and conditions of Plaintiffs Steve Namnath, and all others similarly situated, as set forth herein in Count I.

161. As a direct and proximate result of the aforesaid injuries, Steve Namnath, and all others similarly situated, have suffered injuries as set forth herein in Count I.

WHEREFORE, Plaintiff Steve Namnath, individually and on behalf of all others similarly situated,

demand judgment against Defendants Genzyme Corporation and Mount Sinai School of Medicine of the City University of New York, jointly and severally in an amount in excess of $75,000.00, together with costs of suit. JURY TRIAL DEMANDED.

COUNT XVI: LOSS OF CONSORTIUM

BARBARA J. CARIK, EARL HOCHENDONER, CHERYL BRITTON, ERIN MASULA, WENDY STANZIANO, STACY LADD, HEIDI WITTENBERG AND DARLENE COOKINGHAM, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED v. GENZYME CORPORATION AND MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK

162. Paragraphs 1 through 161 of the Complaint are incorporated as if set forth fully at length herein.

163. As a direct and proximate result of the injuries sustained by their spouses, Plaintiffs have been damaged as follows:

a. Plaintiffs have been and will continue to be compelled to expend large sums of money for medical care, supplies, appliances, and medicine;

b. Plaintiffs have been and may be compelled to expend large sums of money for hiring help to perform household duties previously performed by their spouses; and

c. Plaintiffs have been and will be deprived of their spouse's aid, comfort, assistance, companionship, and consortium.

WHEREFORE, Plaintiffs Barbara J. Carik, Earl Hochendoner, Cheryl Britton, Erin Masula, Stacy Ladd, Wendy Stanziano, Heidi Wittenberg, and Darlene Cookingham, individually and on behalf of all others similarly situated, demand judgment against Defendants Genzyme Corporation and Mount Sinai School of Medicine of the City University of New York, jointly and severally in an amount in excess of $75,000.00, together with treble damages and costs of suit. JURY TRIAL DEMANDED.

Respectfully submitted,

/s/ Matthew L. Kurzweg

Matthew L. Kurzweg, Esq.
Pa.I.D. 76462

/s/ C. Allen Black, Jr.

C. Allen Black, Jr., Esquire
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CERTIFICATE OF SERVICE

I, Matthew L. Kurzweg, Esq., counsel for Plaintiffs, hereby certify that I have served a true and correct copy of the foregoing Amended Complaint upon the following counsel of record by of the Court's CM/ECF filing system this 25th day of April, 2011:

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/s/ Matthew L. Kurzweg
Matthew L. Kurzweg
Attorney for Plaintiffs